

REMARKS:

Claims 1 and 7 are in the case and presented for consideration.

Initially, applicants thank the Examiner for the telephone interview on June 2, 2004.

The substance of the interview on that date was as follows.

The Examiner indicated that in his previous Office Action, a reference was cited with an incorrect author name, noting that the name Xia should be changed to Gourlet. The Examiner asked whether applicants received a correct copy of the intended reference. Peter C. Michalos, attorney for applicants, indicated that the correct reference was received with the Office Action mailed on November 17, 2003.

Turning to the present Office Action, the Examiner indicates that it has not entered the substitute specification filed on March 17, 2004. Applicants note that a substitute specification was not filed on March 17, 2004. On March 17, 2004, applicants filed a response to an Office Action in which the specification was amended by presenting replacement paragraphs marked up to show changes made relative to the immediate prior version in conformity with 37 C.F.R. 1.121. The marked up replacement paragraphs are shown on pages 3-5 of the amendment. Pursuant to a telephone conversation on September 21, 2004, Examiner Wu had indicated that the amendment to the specification on March 17, 2004 was entered and that the current objection is an error. Accordingly, any further objections derived from this error are overcome.

The sequence listing has been objected to for failing to explain the source of genetic material in identifier <220> and for other miscellaneous errors as to the form of the sequence. Applicants have made appropriate corrections and enclose a revised sequence listing.

Claim 1 was rejected under 35 U.S.C. 102(b) as being anticipated by Fishbein, et al. In particular, the Examiner states that Fishbein teaches pseudopeptide VPAC1 receptor agonists placed in an HPLC loading buffer.

Claim 1 has been rewritten to clarify the claimed invention and now recites an "effective pharmaceutical unit dosage formulation of vasoactive intestinal peptide/pituitary adenylate cyclase-activating peptide receptor agonist." This limitation is supported by the specification on page 13, paragraph 53, which states that "active ingredients may be formulated in unit dosage" for administration with a pharmaceutically acceptable carrier. Examples of effective unit dosage formulation are given throughout the specification in milligrams per kilogram of body weight, such as described on page 15, paragraph 59.

Applicants have also added new claim 7, which is substantially similar to claim 1, and further recites an effective dosage of the active ingredient formulation in milligrams per kilogram of body weight. Applicants note that the new unit dosage formulation limitation in claim 1 and unit dosage formulation limitation in new claim 7 are structural limitations drawn to the form of a composition.

Applicants submit that rewritten claim 1 is not new matter and should not require any further searching from the Examiner, since original claim 1 required a pharmaceutically acceptable carrier and recited a "pharmaceutical composition" in the preamble. Applicants logically deduce that the Examiner has already searched pharmaceutical compositions and, therefore, searched any patents which would include a pharmaceutical unit dosage formulation of the claimed active ingredient.

Applicants also respectively submit that Fishbein fails to teach or suggest at least one limitation recited in claim 1.

Claim 1 recites:

a pharmaceutical composition for the treatment and/or prevention of septic shock, comprising an effective pharmaceutical unit dosage formulation of vasoactive intestinal peptide/pituitary adenylate cyclase-activating peptide receptor agonist with a pharmaceutically acceptable carrier.

Fishbein fails to teach a pharmaceutical composition comprising "an effective pharmaceutical unit dosage formulation of vasoactive intestinal peptide/pituitary adenylate cyclase-activating peptide receptor agonist." In fact, Fishbein fails to teach or suggest any pharmaceutical formulation at all.

The Examiner cites Fishbein for teaching purification of pseudopeptide VPAC1 receptor agonists in chromatography, wherein the pseudopeptide is placed in HPLC loading buffer. The Examiner also cites Fishbein for teaching the addition of vasoactive intestinal peptide to a suspension of pancreatic acini and incubation buffer, containing BSA, to further study the binding of VIP to acini.

Applicants note that Fishbein is a research article in which the purification is performed only so that the properties of the pseudopeptide can be further studied (e.g., amylase release measurement). Likewise, the amount of VIP added to incubation buffer is only for the purpose of researching the binding properties of VIP. Thus, Fishbein fails to teach or suggest an effective pharmaceutical unit dosage formulation of vasoactive intestinal peptide/pituitary adenylate cyclase-activating peptide receptor agonist, as recited in claim 1. Fishbein does not teach or suggest any kind of pharmaceutical unit dosage formulations for pharmaceutical or therapeutic treatment.

New claim 7 is also believed to be patentable for the same reasons as stated above for claim 1, since both claims require a unit dosage formulation.

Claim 7 further requires a dosage of the active ingredient in milligrams per kilogram of body weight, which is not taught or suggested by Fishbein, et al.

Claim 1 was also rejected under 35 U.S.C. 102(a) as being anticipated by Gourlet, et al. According to the Examiner, Gourlet discloses purification by chromatography, in which VPAC1 agonists are placed in a loading buffer. Also, the Examiner indicates that Gourlet discloses use of 1% BSA in binding assays. Thus, like in Fishbein, the VPAC1 agonists are only used in the study of binding properties for example, and is not provided in an effective pharmaceutical unit dosage formulation for pharmaceutical or therapeutic administration. Therefore, Gourlet fails to teach or suggest the recited unit dosage formulation.


Further, claim 7 is patentable because it recites not only a unit dosage formulation, but also that the dosage is in milligrams per kilogram body weight.

Accordingly, the application and claims are believed to be in condition for allowance, and favorable action is respectfully requested. No new matter has been added.

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If any issues remain which may be resolved by telephonic communication, the Examiner is respectfully invited to contact the undersigned at the number below, if such will advance the application to allowance.

Respectfully submitted,


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